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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,833	11/30/2001	Philip E. Thorpe	4001.002299	8102

23720 7590 03/28/2005

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,833	THORPE ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-9,23-27 and 41-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-26 and 72-74* is/are allowed.

6)☒ Claim(s) *4-9,24,27,41-71 and 75-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Thorpe et al.
Date of Priority: 07/13/1998

DETAILED ACTION

The Amendment filed on 12/13/2004 in response to the previous Non-Final Office Action (09/08/2004) is acknowledged and has been entered. The terminal disclaimer filed on 12/13/2004 has been considered and approved.

After reviewing Applicants arguments pertaining to the restriction requirement (pages 24-27, 12/13/2004), the examiner has withdrawn the finality of the restriction requirement and has rejoined claims 52, 60, 66 and 67.

Thus, Claims 4-9, 23-27, 41-82 are currently pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statements filed 10/29/2004, 11/19/2004, 12/28/2004 and 2/01/2005 are acknowledged and have been considered. A signed copy of the IDS is attached hereto.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Previous Rejections:

All rejections and or objections are withdrawn in view of applicant's amendments.

New Rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-9, 24, 27, 41-71 and 75-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 17-20, 27-54 of U.S. Patent No. 6,783,760. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating an animal having a vascularized tumor with at least an agent that binds to an aminophospholipid and at least a second anti-tumor agent, wherein the agent is an antibody claimed in the patent appears to fall within the same scope of the method of treating an animal having a vascularized tumor with at least an antibody that binds to an aminophosholipid and at least a second therapeutic agent claimed in the application being examined and, therefore, a patent to a method of treating an animal having a vascularized tumor with at least an antibody that binds to an aminophosholipid and at least a second therapeutic agent would necessarily, extend the rights of a method of treating an animal having a vascularized tumor with at least an agent that binds to an aminophospholipid and at least a second anti-tumor agent, wherein the agent is an antibody should the application being examined issue as a patent after the conflicting patent.

Claims 4-9, 41, 49-51, 53, 57-58, 61, 68-71, 75-78, 80-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-11, 28-29 and 43 of U.S. Patent No. 6,312,694. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating an animal having a vascularized tumor with at least an agent that binds to an aminophospholipid and at least a second anti-tumor agent, wherein the agent is an antibody claimed in the patent appears to fall within the same scope of the method of treating an animal having a vascularized tumor with at least an antibody that binds to an aminophosholipid and at least a second therapeutic agent claimed in the application being examined and, therefore, a patent to a method of treating an animal having a vascularized tumor with at least an antibody that binds to an aminophosholipid and at least a second therapeutic agent

would necessarily, extend the rights of a method of treating an animal having a vascularized tumor with at least an agent that binds to an aminophospholipid and at least a second anti-tumor agent, wherein the agent is an antibody should the application being examined issue as a patent after the conflicting patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4, 6-7, 9, 25, 41, 49-50, 57-58, 61, 64-65, 67-68, 71, 73, 75-78 and 80-82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoit (IDS, U.S. 6,300,308, 12/31/1997) in combination with Hudziak *et al.* (U.S. 5,725,856, 1998).

Schroit discloses methods for using lipid-specific antibody compositions, including those specific for PS (phosphatidylserine), in a variety of diagnostic and therapeutic regimens such as for the treatment of cancer in a human, wherein the cancer is characterized by the presence of PS on the external leaflet of the tumor (column 2, lines 49-52; column 8, lines 41-44; and column 16, lines 38-44). With regards to the antibody, the patent teaches (column 4, lines 38-48) that the antibody can be a monoclonal antibody or a humanized antibody specific for PS. Schroit further teaches that the antibodies may be used simultaneously in combination with a second anti-cancer agent such as diphtheria toxin (column 8, lines 65-67). Moreover, the patent discloses that the antibody compositions can be administered either intravenously, parentally or intraperitoneally (column 17, lines 16-18).

Schroit does not teach a method of treating cancer using an anti-PS antibody in combination with other chemotherapeutic or anti-angiogenic agents.

Hudziak *et al.* teach a method of inhibiting growth of tumor cells which over express a growth factor receptor by administering antibodies either alone or in combination with other cytotoxic factors (abstract). Specifically, the patent teaches (column 6, lines 56-65) that a cytotoxic

factor exerts a cytostatic (cell growth suppressive) and cytotoxic (cell destructive) effect and include, but are not limited to, chemotherapeutic drugs such as 5 fluorouracil, actinomycin D, doxorubicin and vinblastine or anti-angiogenic agents such as TNF-α.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine a chemotherapeutic or anti-angiogenic agents with antibodies. As evidenced by Hudziak *et al.*, it is well known in the art that cytotoxic factors, such as chemotherapeutics or anti-angiogenic agents, can be used in combination with antineoplastic antibodies to achieve an additive effect (column 7, lines 1-5). Thus, one of ordinary skill in the art would have a reasonable expectation that by combining chemotherapy with the anti-phosphatydilserine antibodies used by Schroit, one would achieve enhanced antineoplastic effects. In addition, it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose; idea of combing them flows logically from their having been individually taught in prior art. In *re Kerkhoven*, 205 USPQ 1069 (CCPA) 1980.

Note: There is no prior art that teaches or suggests a method of treating a tumor comprising administering a trimer, multimer or dimer of an anit-phospholipid antibody in combination with a chemotherapeutic agent. In addition, there is not prior art that teaches or suggests the an image of the vasculature of a vascularized tumour by administration of a diagnostically effective amount of a detectably-labeled antibody. The closest prior art is Schroit, whom teaches the treatment of cancer using an anti-aminophospholipid antibody. Thus, claims 23-26 and 72-74 appear to be free of the prior art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/21/05